# **Complete Summary**

#### **GUIDELINE TITLE**

Use of ultrasound for the diagnosis of deep venous thrombosis in asymptomatic inpatients: A recommendation statement from the University of Pennsylvania Health System Center for Evidence-based Practice.

# **BIBLIOGRAPHIC SOURCE(S)**

Agarwal R, Carpenter J, Davis J, Hanson CW, Iyoob S, Langer J, Maloney-Wilensky E, Mohler E, Reilly P, Umscheid CA, Wernsing D, Williams K, University of Pennsylvania Health System Ultrasound Task Force. Use of ultrasound for the diagnosis of deep venous thrombosis in asymptomatic inpatients: a recommendation statement from the University of Pennsylvania Health System Center for Evidence-based Practice. Philadelphia (PA): University of Pennsylvania Health System; 2007 Feb 21. 39 p. [38 references]

#### **GUIDELINE STATUS**

This is the current release of the guideline.

# **COMPLETE SUMMARY CONTENT**

SCOPE

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

**DISCLAIMER** 

#### SCOPE

## DISEASE/CONDITION(S)

Deep venous thrombosis (DVT)

#### **GUIDELINE CATEGORY**

Diagnosis Evaluation Prevention Risk Assessment Screening

## **CLINICAL SPECIALTY**

Critical Care
Internal Medicine
Neurological Surgery
Neurology
Orthopedic Surgery
Pulmonary Medicine
Radiology
Surgery

## **INTENDED USERS**

Health Care Providers
Hospitals
Managed Care Organizations
Physician Assistants
Physicians
Utilization Management

## **GUIDELINE OBJECTIVE(S)**

To provide a guideline for the indications of ultrasound use for the diagnosis of deep venous thrombosis (DVT) in asymptomatic inpatients

### **TARGET POPULATION**

Adult inpatients asymptomatic for deep venous thrombosis

#### INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Color duplex ultrasound
- 2. D-dimer assay (considered, but not recommended)
- 3. Risk scores based on history and physical
- 4. Routine thromboprophylaxis

#### **MAJOR OUTCOMES CONSIDERED**

- Test characteristics (i.e., sensitivity, specificity, predictive values) of color duplex ultrasound, D-dimer assays, and risk scores based on history and physical for the diagnosis of deep venous thrombosis (DVT) in asymptomatic inpatients
- The association of ultrasound use and risk score directed anticoagulation with the incidence of DVT, pulmonary embolism (PE), bleeding or death

## **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

# **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

Center representatives performed a search of MEDLINE and the Cochrane libraries for systematic reviews, meta-analyses, prospective clinical trials and diagnostic studies evaluating the use of color duplex ultrasound in Western adult inpatients with no signs or symptoms of deep venous thrombosis (DVT). The MEDLINE database was searched using the terms "venous thrombosis [MeSH]" AND ("asymptomatic[kw]" OR "surveillance[kw]" OR ("screening[kw]" OR "mass screening[MeSH]") limited to humans and English language and "all adult (19 plus years)" and (clinical trial or controlled clinical trial or meta analysis or randomized controlled trial).

The Cochrane libraries (The Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, and The Cochrane Central Register of Controlled Trials) were searched using the terms "ultrasound" in Title, Abstract or Keywords AND "venous thrombosis" in Title, Abstract or Keywords.

In total, 62 studies were initially identified from the MEDLINE and Cochrane databases of which 6 studies were ultimately used for the review.

Local guidelines were also reviewed (see Appendices 1 and 2 in the original guideline document), and a systematic review of national guidelines was performed using the National Guideline Clearinghouse and following criteria:

Keyword: deep venous thrombosis Methods Used to Assess the Quality and Strength of the Evidence: Weighting According to a Rating Scheme (Scheme Given), Weighting According to a Rating Scheme (Scheme Not Given) Methods Used to Analyze the Evidence: Meta-Analysis, Meta-Analysis of Individual Patient Data, Meta-Analysis of Randomized Controlled Trials, Meta-Analysis of Summarized Patient Data, Review, Review of Published Meta-Analyses, Systematic Review, Systematic Review with Evidence Tables Age Range: Adult (19 to 44 years), Aged (65 to 79 years), Aged (80 and over), Middle Age (45 to 64 years) Publication Date(s): 2006, 2005, 2004, 2003, 2002, 2001

The search was limited to guidelines developed in the United States. In total, three guidelines were found. In addition, Task Force participants recommended the use of two other guidelines (Eastern Association for the Surgery of Trauma [Trauma EAST] Group and Physicians' Information and Education Resource [PIER]).

The guidelines were used in a number of ways. First, the reference lists of the five guidelines were searched using the criteria established for the MEDLINE and Cochrane searches above, but no additional studies meeting the inclusion criteria

were found. Next, the task force abstracted guideline recommendations that addressed the question of interest (see Appendix 4 in the original guideline document). In addition, the task force searched the reference lists of the two leading guidelines (the Seventh American College of Chest Physicians [ACCP] Guideline and the Trauma East Guideline) for references addressing the risk of incident DVT and pulmonary embolism (PE) in populations receiving anticoagulation. Risk groups, risk of venous thromboembolism (VTE), method of ascertainment, follow up period, and number of studies were abstracted from the relevant references into an evidence table (Table 7 in the original guideline document). In a separate table, the task force further abstracted the risk of all VTE, all DVT, Proximal DVT, Distal DVT, and PE from all randomized clinical trials (RCTs) using low molecular weight heparin (LMWH) in  $\geq 1$  arm from risk groups that demonstrated a risk of VTE of >20% as ascertained by venography (Table 8 in the original guideline document). In total, data from 28 orthopedic studies, 2 neurosurgery studies, 2 major trauma studies, and 1 spinal cord injury study were abstracted.

## **NUMBER OF SOURCE DOCUMENTS**

6 studies from the MEDLINE and Cochrane databases

5 guideline documents

33 studies identified through review of guideline documents

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The following grades of overall quality developed by the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) working group were used to grade the overall quality of evidence for each outcome:

**High** - Further research is very unlikely to change confidence in the estimate of effect

**Moderate** - Further research is likely to impact confidence in the estimate of effect and may change the estimate

**Low** - Further research is very likely to impact confidence in the estimate of effect and is likely to change the estimate

**Very low** - Any estimate of effect is very uncertain

## METHODS USED TO ANALYZE THE EVIDENCE

#### **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

The quality of the individual studies was assessed using a four point diagnostic study criteria score for diagnostic studies and a seven point modified Jadad score for randomized clinical trials (RCTs). Following data abstraction into evidence tables, pooling of results was done when appropriate, and the results were reviewed with task force members.

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

At the first Task Force meeting, Center for Evidence-Based Practice (CEP) procedures were introduced, as were local ultrasound use statistics and local guidelines (see Appendices 1–3 in the original guideline document). Next, the results of a systematic review performed by CEP to address the risks and benefits of color duplex ultrasound in the diagnosis of deep venous thrombosis (DVT) in asymptomatic inpatients were presented.

For consideration of the association of ultrasound use with the incidence of DVT, pulmonary embolism (PE), bleeding or death, the intervention was not restricted to color duplex ultrasound but instead was extended to studies assessing the association of any mode of ultrasound with incident DVT, PE, bleeding or death as there were no studies evaluating the association of color duplex with these outcomes. When evaluating risk scores based on history and physical, symptomatic patients were included.

The important trade-offs between the potential benefits and harms of the interventions were examined, and levels of recommendations were used (See "Rating Scheme for the Strength of the Recommendations").

The draft guideline was finalized using methods of consensus development.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

**Strong** - Test should or should not be used for routine surveillance of deep venous thrombosis (DVT)

Weak - Test may be useful for surveillance of DVT in certain circumstances

**Further research** - No evidence exists for the usefulness of test in surveillance of DVT

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Internal Peer Review

#### **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

The guideline was approved by the chief medical officer (CMO) of each hospital in the University of Pennsylvania Health System (UPHS) for dissemination and implementation.

#### **RECOMMENDATIONS**

#### MAJOR RECOMMENDATIONS

Definitions for the quality of evidence (high, moderate, low, very low) and strength of recommendations (strong, weak, further research) are repeated at the end of the Major Recommendations.

# Use of Ultrasound for the Diagnosis of Deep Venous Thrombosis in Asymptomatic Patients

- 1. Routine thromboprophylaxis instead of ultrasound surveillance should be the cornerstone of venous thromboembolic event (VTE) prevention in asymptomatic inpatients. The Anticoagulation Task Force provides guidelines for routine thromboprophylaxis. (Strong Recommendation, Moderate to Low Quality Evidence)
- 2. Ultrasound surveillance of the bilateral proximal lower extremities may be most appropriate in situations where thromboprophylaxis is not possible. (Weak Recommendation, Very Low Quality Evidence)
- 3. Ultrasound surveillance of the bilateral proximal lower extremities may also be appropriate in patients at the highest risk of deep venous thrombosis (DVT) or pulmonary embolism (PE) despite thromboprophylaxis (i.e., spinal cord injury patients, major trauma patients with high severity scores, and the highest risk orthopedic patients), and should likely be performed no more frequently than approximately once weekly. (Weak Recommendation, Very Low Quality Evidence)
- 4. Color duplex ultrasound has adequate sensitivity and specificity to diagnose DVT in asymptomatic inpatients, and should be the test of choice for the diagnosis of DVT in asymptomatic inpatients when compared with D-Dimer assays or risk scores based on history and physical. (Strong Recommendation, Moderate Quality Evidence)
- 5. D-Dimer assays should not be used to diagnose DVT in asymptomatic inpatients. (*Strong Recommendation, Moderate Quality Evidence*)

#### Definitions:

#### **Quality of Evidence**

The following grades of overall quality developed by the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) working group were used to grade the overall quality of evidence for each outcome:

**High** - Further research is very unlikely to change confidence in the estimate of effect

**Moderate** - Further research is likely to impact confidence in the estimate of effect and may change the estimate

Low - Further research is very likely to impact confidence in the estimate of effect and is likely to change the estimate

**Very low** - Any estimate of effect is very uncertain

# **Strength of Recommendations**

**Strong** - Test should or should not be used for routine surveillance of deep venous thrombosis (DVT)

Weak - Test may be useful for surveillance of DVT in certain circumstances

**Further research** - No evidence exists for the usefulness of test in surveillance of DVT

# **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

# TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## **POTENTIAL BENEFITS**

Appropriate use of ultrasound for the diagnosis of deep venous thrombosis in asymptomatic patients

## **POTENTIAL HARMS**

Not stated

## **QUALIFYING STATEMENTS**

# **QUALIFYING STATEMENTS**

Recommendations are based on an assessment of the overall quality of evidence for each outcome examined as well as the important trade-offs between the potential benefits and harms of the interventions examined, and is a guideline that should inform, but not replace, expert clinical judgment.

## **IMPLEMENTATION OF THE GUIDELINE**

#### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

## **IOM CARE NEED**

**Getting Better** 

#### **IOM DOMAIN**

Effectiveness

# **IDENTIFYING INFORMATION AND AVAILABILITY**

## **BIBLIOGRAPHIC SOURCE(S)**

Agarwal R, Carpenter J, Davis J, Hanson CW, Iyoob S, Langer J, Maloney-Wilensky E, Mohler E, Reilly P, Umscheid CA, Wernsing D, Williams K, University of Pennsylvania Health System Ultrasound Task Force. Use of ultrasound for the diagnosis of deep venous thrombosis in asymptomatic inpatients: a recommendation statement from the University of Pennsylvania Health System Center for Evidence-based Practice. Philadelphia (PA): University of Pennsylvania Health System; 2007 Feb 21. 39 p. [38 references]

#### **ADAPTATION**

Not applicable: The quideline was not adapted from another source.

#### **DATE RELEASED**

2007 Feb

#### **GUIDELINE DEVELOPER(S)**

University of Pennsylvania Health System - Academic Institution

# **SOURCE(S) OF FUNDING**

University PA Health System

#### **GUIDELINE COMMITTEE**

University of Pennsylvania Health System (UPHS) Ultrasound Task Force

#### **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

Rajender Agarwal, Jeffery Carpenter, Julia Davis, C. William Hanson, Suzanne Iyoob, Jill Langer, Eileen Maloney-Wilensky, Emile Mohler, Pat Reilly, Craig A. Umscheid, David Wernsing, Kendal Williams

# FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Voting members of the Task Force were free of conflicts of interest.

#### **GUIDELINE STATUS**

This is the current release of the guideline.

#### **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) by request. Please contact <u>Katie.thomas@uphs.upenn.edu</u>.

#### **AVAILABILITY OF COMPANION DOCUMENTS**

None available

# **PATIENT RESOURCES**

None available

### **NGC STATUS**

This NGC summary was completed by ECRI Institute on April 2, 2008. The information was verified by the guideline developer on April 30, 2008.

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